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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,696	10/05/2006	Edith Gardiner	42-000400US	5276
22798 7590 09/22/2008 QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501				
			EXAMINER	
			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	
			MAIL DATE	DELIVERY MODE
			09/22/2008 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/572,696

Applicant(s)

GARDINER ET AL.

Examiner

RUIXIANG LI

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 106, 107, 122, 125-128, 139, 151 and 152 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 106, 107, 122, 125-128, 139, 151, and 152 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claim 106, drawn to a method of determining a compound that is a modulator of Y receptor associated differentiation of a mesenchymal stem cell or bone marrow stromal cell into an osteoblast-type cell.
- II. Claim 107, drawn to a method of determining a compound that is a modulator of Y receptor associated differentiation of a mesenchymal stem cell or bone marrow stromal cell into an adipocyte-type cell.
- III. Claims 122 and 125-128, drawn to a non-naturally occurring transformed animal having reduced expression of multiple receptors in a cell or tissue by virtue of carrying insertions in multiple Y receptor-encoding genes wherein said animal has modulated bone remodeling activity.
- IV. Claim 139, drawn to a method of treatment of aberrant bone remodeling in a subject in need thereof comprising isolating a mesenchymal stem cell or bone marrow stromal cell from a human or animal subject, treating the mesenchymal stem cell or bone marrow stromal cell with a compound that modulates Y

receptor associated differentiation under conditions sufficient to induce differentiation of the cells into osteoblast type cell and introduce the osteoblast type cell into the subject in need of treatment.

V. Claims 151 and 152, drawn to a method comprising administering a compound to the non-naturally occurring transformed animal and determining bone remodeling activity.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is considered to be a method of determining a compound that is a modulator of Y receptor associated differentiation of a mesenchymal stem cell or bone marrow stromal cell into an osteoblast-type cell.

The special technical feature of Group II is considered to be a method of determining a compound that is a modulator of Y receptor associated differentiation of a mesenchymal stem cell or bone marrow stromal cell into an adipocyte-type cell.

The special technical feature of Group III is considered to be a non-naturally occurring transformed animal having reduced expression of multiple receptors in a cell or tissue by virtue of carrying insertions in multiple Y receptor-encoding genes wherein said animal has modulated bone remodeling activity.

The special technical feature of Group IV is considered to be a method of treatment of aberrant bone remodeling in a subject in need thereof comprising isolating a mesenchymal stem cell or bone marrow stromal cell from a human or

animal subject, treating the mesenchymal stem cell or bone marrow stromal cell with a compound that modulates Y receptor associated differentiation under conditions sufficient to induce differentiation of the cells into osteoblast type cell and introduce the osteoblast type cell into the subject in need of treatment.

The special technical feature of Group V is considered to be a method comprising administering a compound to the non-naturally occurring transformed animal and determining bone remodeling activity.

Accordingly, Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.

3. Furthermore, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are the multiple Y receptors as listed in claims 125 and 126.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because the Y receptors are not regarded as being of similar nature because all the alternatives do not share a common structure and are considered to be distinct chemical identities.

Should applicants elect an invention containing these claims, Applicants are further required under 35 U.S.C. 121 to elect a single group of Y receptors as listed in

claims 125 and 126 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02 (a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (I).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
September 16, 2008